PLANT PROTECTION

EVALUATION OF ACTIVE SUBSTANCES AT EU LEVEL

Procedure with Belgium involved as Rapporteur Member State (RMS) or co-RMS

Federal Public Service **Health, Food Chain Safety and Environment**
Department Plant protection products and Fertilizers

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DOCUMENT INFORMATION

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VERSION HISTORY

Version and date	Point	Changes
Version 1.1 March 2016		Minor changes to the original document
Version 2.0 May 2020	1	Update timelines for process renewal of a.s. approval, taking into consideration amendments of Reg. (EU) No 844/2012
	1, 2 and 3	Reference added to the complementary administrative guidance of EFSA (2019) on submission of dossiers and assessment reports for the peer-review of pesticide active substances (EFSA, 2019)
	6	New fees; reference added to the updated guidance for applicants.
	7	Update of addresses for submission of dossiers
Version 3.0 June 2022	All sections	Overall update, particularly regarding administrative requirements and dossier format (IUCLID), in line with the new EU procedures that have been introduced to implement the Transparency Regulation (EU) 2019/1381. Also updates regarding timelines for process renewal of a.s. approval, taking into consideration Reg. (EU) 2020/1740 (which replaces Reg. (EU) 844/2012), clarification regarding related/integrated MRL applications and update of postal addresses for submission of dossiers.

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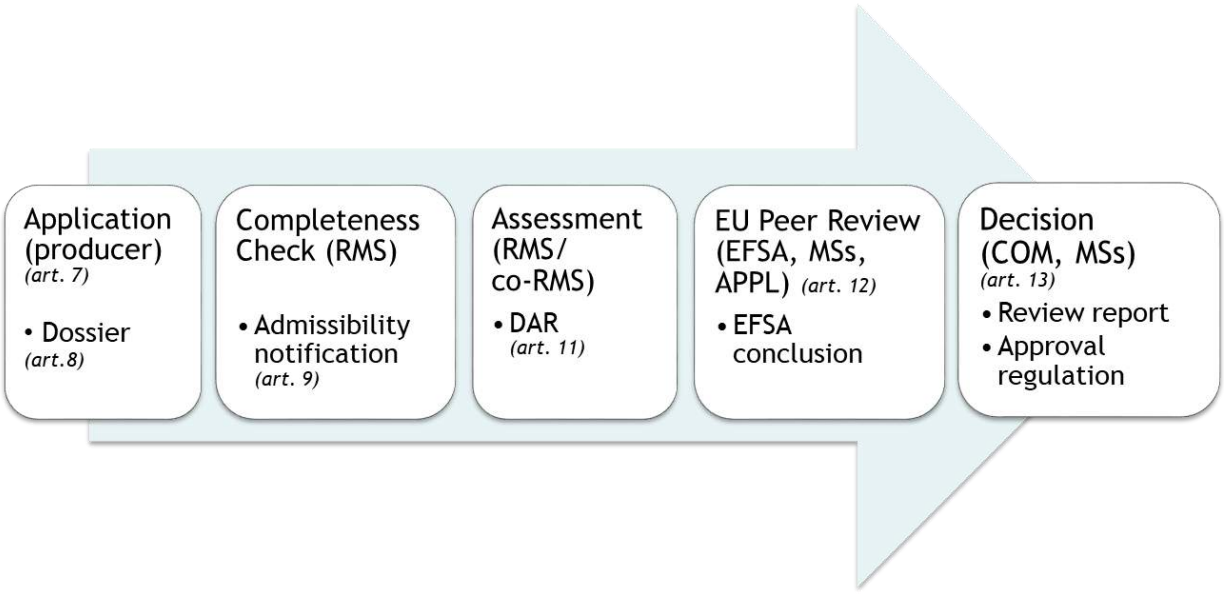
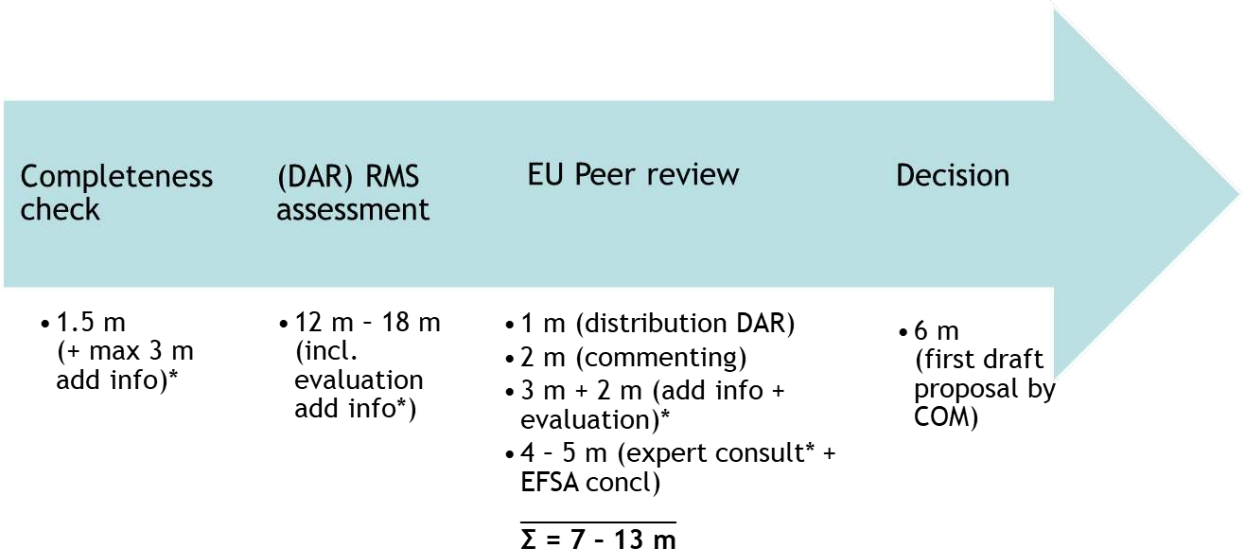
1. Introduction

The EU procedure to be followed for the **approval** of an active substance (or for an amendment to the conditions of an approval) is stipulated in articles 7 to 13 of Regulation (EC) No 1107/2009. The different steps are presented in the scheme here below.

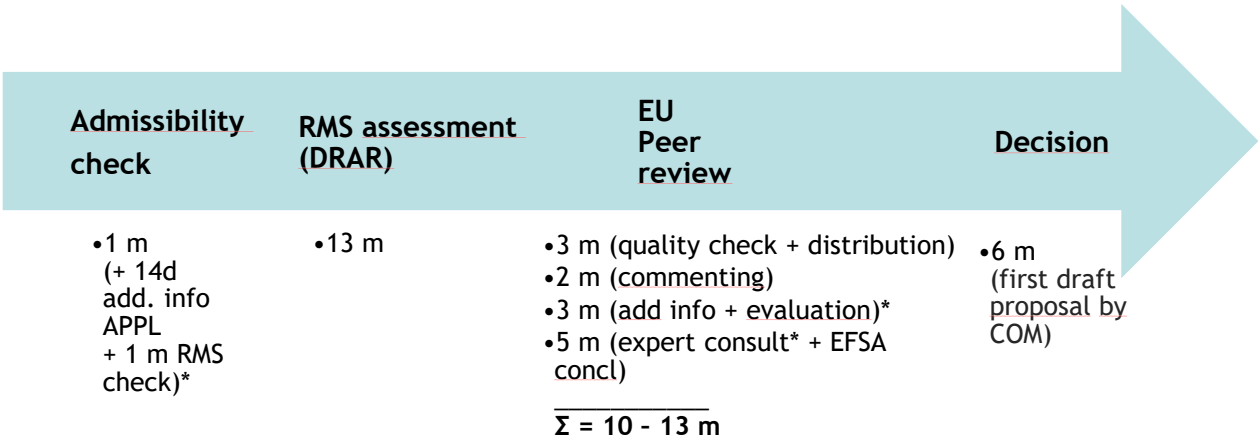


From application to decision on (non-)approval, it takes at least 2.5 years, taking into account the legal timelines as summarised in the scheme below. If additional information is requested from the applicant during the evaluation process and/or an expert consultation is needed – see optional steps marked with * in the scheme – the whole process can take up to approximately 3.5 years.



It is noted that EU Member states (MSs) are only allowed to give a provisional authorisation – i.e. authorisation for placing on the market of a plant protection product containing an active substance not yet approved at EU level – if the decision on approval of that active substance is delayed for more than 3.5 months beyond the legally foreseen deadline (cf. art. 30.1(a) of Reg. (EC) No 1107/2009).

The procedure for the **renewal of approval** of an active substance (often abbreviated as '**AIR**'; Active Ingredient Renewal) is principally the same, but the timelines are somewhat different (see scheme here below). The detailed procedure is established by Reg. (EU) 2020/1740 (which replaces the former Reg. (EU) No 844/2012 from 27 March 2021). More information on the AIR work programmes is available on the website of the European Commission.



A consideration of the proposals on the Harmonised Classification and Labelling (CLH) in accordance with Regulation (EC) No 1272/2008 has been integrated in the procedure for renewal of approval; timelines are aligned as far as possible and a parallel consideration by the European Chemicals Agency (ECHA) is foreseen.

In the following sections here below, a summary is given of the main steps in the procedure and the administrative requirements, as well as some practicalities in case Belgium is involved as RMS or co-RMS. For further details, applicants should consult EFSA's administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the maximum residue level (MRL) procedure (EFSA, 2021)[1].

[1] EFSA, 2021. Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the maximum residue level (MRL) application procedure, EFSA supporting publication 2021:EN-6464. 77 pp. doi:10.2903/sp.efsa.2021.EN-6464

2. Pre-submission

In the case of **new active substances**, the notifier has the possibility to choose the RMS, who will perform the initial evaluation of the dossier and will follow up the dossier up to the decision. In the case of review of existing active substances – e.g. in the framework of the **renewal** of approval – the European Commission (EC) establishes a legislation in which each substance is allocated to a Rapporteur Member State (RMS) and co-Rapporteur Member State(s) (co-RMS).

Generally, before submitting an application for active substance approval (renewal), the potential applicant should register in EFSA's portal (**Connect EFSA**). Through this portal, the applicant should do the mandatory **notification of studies (NoS)**[2] commissioned or carried out in view of the application. Via this online platform, the applicant may also, optionally, request **general** and non-committing **pre-submission advice (GPSA)** directly from EFSA, preferably at least 6 months before the envisaged submission date of the application (see EFSA administrative guidance 2021 – chapter 2.1). For intended renewal applications, there is an additional obligation for notification (to EFSA) of intended studies, at least 5 months before the date of the intended commissioning of the studies. This list of intended studies (incl. study designs) will be subject to a public consultation and EFSA will eventually provide **renewal pre-submission advice (RPSA)** to the potential applicant (see EFSA administrative guidance 2021 – chapter 2.4). All pre-submission activities and contacts with EFSA will be linked to a unique pre-application identification number (**PA-ID**) allocated by EFSA.

Generally, the company that intends to submit an application for which Belgium is (candidate) RMS or co-RMS, is invited to contact the Belgian competent authority to discuss the time schedules for submission, the practical details of the submission, the organisation of a pre-submission meeting etc. Contact: BE contact person EU applications

[2] Both potential applicants and laboratories/testing facilities have the obligation to notify, without delay, information to EFSA about all studies commissioned or carried out (as of 27 March 2021) to support an EU application (see EFSA administrative guidance 2021 – chapter 2.5).

3. Submission of the application

The application and the supporting dossier have to be prepared by the applicant using the **IUCLID** (International Uniform ChemicaL Information Database) software. Once prepared, the dossier must be uploaded through a central submission system (**ECHA Cloud Services**). EFSA, the European Commission and the competent authorities of the EU Member States have access to this secure online platform, which makes separate submissions to all Member States redundant.

However, if Belgium acts as RMS, the applicant is kindly invited to send also a **paper copy** of (a part of) its dossier to the following two facilities of the BE competent authority that are involved in the assessment of the dossier (see postal addresses under Contact):

- Federal Public Service Health, Food Chain Safety and Environment (**FPS HFCSE**): a paper copy of the full dossier;
- **Sciensano:** a paper copy of the human toxicology part of the dossier. For micro-organisms or associated (e.g. antibodies, RNAi), a paper copy of the full dossier is requested.

To facilitate the handling and assessment of the dossier by Belgium (as RMS), the applicant is kindly invited to provide an additional **electronic copy** to RMS Belgium (either on CD/DVD together with the paper copy submission or via a cloud transfer system with notification via e-mail to our secretariat (secret.div1@health.fgov.be)[3].

More details on the preparation and submission of an application are available in EFSA's administrative guidance (EFSA, 2021 – chapters 2.6 and 3). A summary of the tools that applicants are expected to use in the preparation of the application (e.g. IUCLID Manual) and subsequent phases is also available in the toolkit on the EFSA website.

More information regarding dossier requirements, EU technical and procedural guidelines can be found on the website of the European Commission (DG SANTE). Relevant scientific peer-reviewed open literature shall also be included in the dossier, in accordance with the EFSA guidance[4].

[3] The e-mail must clearly state all the information with reference to any link or attachment.

[4] European Food Safety Authority; Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (OJ L 309, 24.11.2009, p. 1-50). EFSA Journal 2011;9(2):2092. [49 pp.]. doi:10.2903/j.efsa.2011.2092. Available online: www.efsa.europa.eu

When preparing the dossier, the applicant should pay particular attention to the following aspects with regard to format:

- Literature search:
  - report to be submitted in a transportable format, i.e. either Microsoft Word (MSW) or equivalent (since pdf-file conversion is usually causing problems for extraction of the data to the DAR);
  - obtained relevant articles to be submitted to the RMS;
  - rejected articles: references to be compiled in a separate Excel-file.

- ED assessment:
  - to be performed according to the template of the Guidance document of EFSA/ECHA (see https://www.efsa.europa.eu/en/efsajournal/pub/5311)
  - The output includes:
    (i) a MSW version of the ED assessment as proposed by the notifier, and submitted in the format as imposed in Annex I issued by EFSA (see supporting information in https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2019.EN-1612) («Template for presentation of the assessment of endocrine disrupting properties»)
    (ii) the Excel file «Appendix E – Excel template for reporting the available information relevant for ED assessment» (see https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2018.5311)

- In case QSARs[5] are used in order to support the EU dossier for either the active substance, metabolites or impurities, RMS requests at least a rule-based and a statistically based QSAR, as appropriate. The output of these QSAR predictions should be submitted as a whole.
  The notifier should always provide raw data from QSAR as they are generated by the software tool used (output file) and a summary of the results (in MSW format) with a detailed reasoning of acceptance or rejection of the predictions. The output file generated by the tool should be included in the dossier as a stand-alone file (not embedded in text document). If larger datasets have been analysed by the notifier, the input file should be also provided in a format (e.g. Excel) that would allow the RMS to reproduce the simulation.

- Summaries (doc. M) in MSW format

The EFSA guidance (EFSA, 2021) also describes the procedure with regard to **transparency and confidentiality** requirements (e.g. submission and handling of requests for removal of confidential information before publication).

[5] QSAR: Quantitative Structure-Activity Relationship

4. Admissibility check & publication of the dossier

Fees

After submission of the application, the applicant will receive an invoice from the Belgian authority (FPS HFCSE), with the request to pay the corresponding **fees**, to cover the costs associated with the assessment by the Belgian competent authority (BE) as RMS or co-RMS. If needed, BE will contact the applicant to get confirmation on the invoice address.

The fees are stipulated in the Belgian royal decree of 13 November 2011 (as last amended). Reduced fees are applicable when it concerns micro-organisms, viruses, substances of plant or animal origin, repellents, attractants, pheromones or substances included in Annex II of Reg. (EC) No 889/2008 (i.e. substances allowed for plant protection purposes in organic production). An overview on the fees is available in Annex 2 of the Guidance for the applicant of an authorisation of a plant protection product in Belgium.

The payment of the relevant fee(s) is one of the prerequisites to consider an application as admissible.[6] For certain applications, the fee may be split up into several invoices, which are sent by BE to the applicant at different steps in the process. For instance, in the case of evaluation of post-approval 'confirmatory information', an 'application for an amendment to the conditions of an approval' or an application for change of an EU endpoint, a fee is foreseen, which may be followed by an additional fee, in the case an EU peer review is organised by EFSA.

Admissibility check

After receipt of the application, Belgium (as RMS) will assess the **admissibility** of the application in line with the procedure described in EFSA's administrative guidance (EFSA, 2021)[7], particularly chapters 2.6 and 2.7. Beside a completeness check against the data requirements, a verification of compliance with the legal obligations of notification of new studies (prior to submission of the application) will be performed by the RMS. At this stage, also the applicant's confidentially requests are checked (e.g. sanitisation of personal data and justifications for confidentiality requests). Non-compliance with those obligations may result in non-admissibility of the application or in delays in the RMS's evaluation or EFSA's peer review process.

[6] cf. art. 8(1)(d) of Reg. (EU) 2020/1740

[7] EFSA, 2021. Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the maximum residue level (MRL) application procedure (https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2021.EN-6464)

Publication of dossier

Once the application is found admissible, Belgium will notify the applicant, the other EU MSs, the EC and also EFSA[8], who will subsequently publish the non-confidential version of the dossier (and where applicable, a summary of the GPSA provided to the applicant by EFSA) on its website (**OpenEFSA** portal). Subsequently, a public consultation (for 3 weeks; 2 months for renewal applications) will be launched and comments received from third parties will also be made public by EFSA.

[8] fdp@efsa.europa.eu; CC: pesticides.peerreview@efsa.europa.eu

5. Assessment by BE as RMS

At the Belgian competent authority, for each active substance approval (renewal) application, the dossier coordinator is the primary contact person for the applicant and is in charge of the administrative tasks related to the dossier evaluation, i.e. coordinating the contacts with the applicant, organisation of meetings, receipt of documents, and dispatch of evaluations.

Contact: BE contact person EU applications

However, during the evaluation of each individual section, experts of the company can directly discuss technical issues with our experts, via e-mail. However, in order to keep track of all the discussions, the coordinator should be put in CC.

Submission of **additional studies or information** by the applicant during the assessment can only be accepted and taken into account if officially requested by the RMS. Therefore, justification, amount of data, possible submission date, etc. should be discussed with the coordinator of the dossier and with the expert responsible for the specific part. Depending on the application, the RMS has the possibility to grant an additional period for submission of such additional data, but this implies a 'stop-the-clock' in the process (max. 6 months). In the framework of the peer review for renewal of the approval of an a.s., additional information can only be submitted upon formal request by EFSA (cf. art. 13(2) of Reg. (EU) No 2020/1740).

Generally, after completion of each part of the evaluation, the individual experts send their evaluation and questions/remarks to the **applicant** for **feedback and comments**. The aim of this unofficial consultation is to solve some issues before the peer review.

In cases where a co-RMS is involved, Belgium as RMS will also send a first draft of the D(R)AR to the **co-RMS** for **commenting**.

The RMS's first evaluation of the application is reported in a **Draft (Renewal) Assessment Report (D(R)AR**), which eventually is made available to EFSA[9]. Where appropriate, the D(R)AR also includes a proposal for harmonised (re-)classification according to Reg. (EC) No 1272/2008 and will therefore be submitted to ECHA as well.

[9] by uploading to the Pesticides Peer Review workspace on the EFSA Document Management System (DMS) together with a covering e-mail notifying EFSA of the upload (to fdp@efsa.europa.eu with pesticides.peerreview@efsa.europa.eu in CC).

6. EU peer review

Note: In addition to the information and guidance provided below, also EFSA's administrative guidance (EFSA, 2021)[10] should be consulted by applicants.

The evaluation of active substances at EU level consists of a detailed evaluation of the dossier by the RMS (and co-RMS). Afterwards, this evaluation is peer reviewed by the other EU MSs and EFSA. EFSA is responsible for the submission of a consolidated risk assessment of the active substance to the EU Commission. EFSA coordinates the EU peer review process, which is summarized in the scheme here below (cf. art. 12 of Reg. (EC) No 1107/2009).

The timeline between receipt of the comments and the final EFSA conclusion is defined by EFSA.

In the framework of renewal of approval, the timelines for the peer review process are different: see scheme in chapter 1 of this document.

[10] EFSA, 2021. Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the maximum residue level (MRL) application procedure, EFSA supporting publication 2021:EN-6464. 77 pp. doi:10.2903/sp.efsa.2021.EN-6464

Commenting on the D(R)AR

EFSA organises the distribution of the D(R)AR to the other MSs and to the applicant and launches a commenting period, which is also open to the public[11]. Comments have to be provided to EFSA in the format and via the tools prescribed by EFSA (see EFSA's administrative guidance chapter 2.12).

Prior to making the D(R)AR available to the public, EFSA will give the applicant 2 weeks to request that certain parts be kept confidential.

At this stage, the applicant should make sure that additional information that may have been submitted during the preparation of the D(R)AR has been submitted in the form of an updated dossier in IUCLID, following the instructions of the IUCLID user manual. In this way, the additional information is automatically made available to MSs, EFSA and the EC.

All comments received (MSs, public, applicant and EFSA) are compiled by the RMS in a **"Reporting Table"**. The applicant is invited by the RMS to react on the comments compiled and then the RMS gives answers to the questions that have been raised and the applicant's responses. Subsequently, the main actions (such as the expert consultation points and data requirements requests) are agreed in the **kick-off teleconference** organised between EFSA-(co)-RMS-(ECHA-EC).

Comments requiring further assessment or submission of additional clarification/information are transferred by EFSA into an "**Evaluation Table**", which is completed during the next steps of the peer review (see below: evaluation of additional info, expert consultation, written procedure).

The answers to questions can be based on additional information and/or clarification submitted by the applicant (see also below), which the RMS will assess and report in an updated D(R)AR.

[11] via **OpenEFSA** portal

Additional information

In consultation with the RMS and taking into account the comments received from stakeholders (EFSA, MSs, applicant, public), EFSA may ask the applicant to provide additional information, within a certain time period that is set by the legislation and depends on the procedure. This additional information should also be submitted electronically in IUCLID format through the EFSA central submission system.

The RMS will present an evaluation of this additional information in an updated DAR. However, this implies a 'stop-the-clock' (for max. 5 months) in the process. In case of an application for renewal of approval, the 'stop-the-clock' (incl. submission and evaluation) is maximally 3 months.

Experts' consultation

To resolve some specific issues, EFSA may (after having consulted the EC and the RMS) organise an experts' consultation for one or more of the sections (physical/chemical properties and analytical methods, toxicology, residues, environmental fate, ecotoxicology). The experts' consultation takes place via a written procedure, via a telephone-web-conference and/or as physical meeting of EU experts. Discussions are summarised in a "**Discussion Table**".

EFSA conclusion

Based on the D(R)AR and the outcome of the peer review, EFSA prepares a summary of the active substance *"Conclusion on the peer review of the pesticide risk assessment of the active substance* […]*"*

Before finalising, EFSA gives MSs the opportunity to comment on the **draft EFSA conclusion** (and the completed evaluation table) via a **written procedure**. In the case of renewal applications, also the applicant will be given the possibility to submit comments on the draft EFSA conclusion. The final EFSA conclusion is sent to the EC and the RMS and made available to all MSs. However, prior to final publication (EFSA Journal and EFSA website[12]), EFSA will submit it to the applicant for consideration of the need for removal of confidential information. All background documents (e.g. reporting tables, evaluation tables, discussion tables) are – compiled in a **Peer Review Report** – also made publicly available by EFSA.[13]

[12] Publications | EFSA (europa.eu)
[13] Via **OpenEFSA** portal

7. Risk management and decision

Normally, the applicant will be given the opportunity by the EC to provide comments on the EFSA conclusion. However, it should be noted that at this stage, generally no evaluation of technical data is performed.

Each individual substance is discussed in at least two meetings of the Working group of Pesticides Legislation of the Standing Committee on Plants, Animals, Food and Feed (**SCPAFF**). This meeting is chaired by the EU Commission (Team pesticides in the Directorate General SANTE) and attended by representatives of each MS and EFSA. On the basis of the EFSA conclusions, discussions in the meetings, the consultations of several directorates of the European Commission and taking into account the comments from the applicant, the Commission prepares a draft **regulation** for either approval or non-approval (resp. renewal/non-renewal of approval), which is accompanied by a '**review report'** (resp. '**renewal report**') giving some more details on the proposed decision.

Finally, MSs represented at the meeting of the SCPAFF vote on the proposal of the EC. A qualified majority is needed to pass a proposal, which is then published in the Official Journal of the EU.

If no qualified majority in favour of the EC proposal is obtained at the SCPAFF meeting, the proposal is referred to the **appeal committee** – which normally consists of the Permanent Representations of the MSs – where further negotiation and discussions take place in view of reaching a compromise among MSs. More details on this specific procedure and timelines can be found in Regulation (EU) No 182/2011 and Rules of procedure for the appeal committee (2011/C 183/05).

8. Post-approval issues

List of references relied upon

The RMS will prepare a list of references that were considered relied upon for the approval (or for amendment or renewal thereof) of the active substance (cf. art. 60(1) of Reg. (EC) No 1107/2009). Normally, Belgium as RMS will give the possibility to the applicant to verify this list before finalising it.

Eventually, the final list is made available to the EC, other EU MSs and the public via the DG SANTE website, along with the EU review report or EU renewal report. The list serves as basis for applying the provisions related to data protection at national level.

Confirmatory information

In some cases, an active substance is approved under the condition that certain confirmatory information be submitted within a certain time period. The RMS which performed the initial evaluation will also evaluate that confirmatory information and will issue a revised D(R)AR. More details on procedure and timelines are given in guidance document SANCO/5634/2009.

The instructions for submission of confirmatory data to Belgium as RMS are in principle the same as those outlined above for a normal application for approval of the a.s.

Finalisation of reference specification

In cases where an agreement on a harmonised specification of the assessed technical material could not be reached before approval of the active substance, a finalisation of the reference specification must be performed, in view of having a basis enabling equivalence assessments. To allow for this finalisation, further data/information might be required from the applicant who supported approval of the a.s.

Where data in view of finalisation of the reference specification are not already requested as confirmatory information (see above), the specific procedure and timelines as given in guidance document SANCO/6075/2009 ("*on the finalization of the reference specification for technical active substances after the peer review*") should be followed.

Renewal / withdrawal / amendment of existing authorisation of plant protection products

The voted regulation concerning (non-)renewl of approval of active substances stipulates the deadlines for EU MSs to renew, withdraw or amend the existing national authorisations of plant protection products containing the concerned active substance.

After publication of the approval in the Official Journal of the EU, all authorisation holders of plant protection products containing the active substance will receive detailed instructions of the information they have to submit in order to maintain their authorisations.

New authorisation of a plant protection product

Under Reg. (EC) No 1107/2009, a plant protection product can normally not be authorised before the active substance is approved. Theoretically, the examination by the zonal RMS of an application for an authorisation of a PPP containing an a.s. not yet approved shall start as soon as a DAR is available (cf. art. 37.3 of Reg. (EC) No 1107/2009). However, taken into account that the time between the distribution of the DAR and the approval of the a.s. will, in the best case, normally be in a range from 12 to 18 months, the zonal examination of the national application will in practice concur with the EU peer review of the active substance. In this way, the assessment can take into account as much as possible EU peer-reviewed endpoints (EFSA conclusion).

In case the application concerns the same PPP (and the same uses) as the representative formulation evaluated in view of approval of the a.s., a decision on the authorization of the PPP shall be made in the zonal RMS (zRMS) and the other EU MSs within resp. 6 and 10 months after approval of the a.s. (cf. art. 37(3) of Reg. (EC) No 1107/2009).

EU MRL setting

The dossier submitted in view of approval of an a.s. should include a copy of the MRL application relevant to the representative uses (cf. art. 8(1)(g) of Reg. (EC) No 1107/2009). The DAR and the EFSA conclusion would in such case serve as an Evaluation Report and EFSA reasoned opinion, respectively (cf. Reg. (EC) No 396/2005, art. 8 resp. art. 11). However, also MRL applications for relevant uses other than the representative uses can be included in the EU approval dossier, in view of integrating to the extent possible the MRL setting for these additional uses in the a.s. approval process, which means a benefit for the authorisation holder, as well as for EFSA, MSs and EC (avoid duplication of work). Of course, this does not undermine the concept of the representative uses, nor does it lead to the need to submit for these other uses a risk assessment in the areas other than those needed for the MRL setting. This means the additional uses will be considered separately in the DAR and the EFSA conclusion and solely from a residue perspective for MRL setting purposes and will have no impact on the decision on approval of the active substance.

As explained in EFSA's administrative guidance (EFSA, 2021 – chapters 3.13 and 4) and further specified in the introduction of EFSA's MRL Applications Manual (see latest version on EFSA **toolkit**), when the applicant submits an MRL application as part of an approval or renewal process, a separate dossier (MRL submission) should be created in IUCLID. The dossier supporting the approval or renewal process and the one supporting the MRL application should be provided at the same time, but submitted separately in the EFSA central submission system. For technical reasons, the MRL submission will have to be done before the dossier submission to allow the system to link the two items.

However, exceptions are cases where:

- the GAP(s) relevant for the MRL application is/are identical to the representative uses of the approval/renewal dossier;
- when it concerns a proposal to amend the existing residue definition;
- when it concerns a proposal for inclusion of an active substance in Annex IV of Reg. (EC) No 396/2005.

In those cases, it is not required to create a separate MRL dossier in IUCLID, but the MRL or residue definition proposals should be highlighted in the dossier header and/or in the appropriate endpoint summaries. Further details are provided in EFSA's MRL Applications Manual.

9. Contact

Belgian competent authority

Contact person details			
BE Contact person EU applications	Mr Philippe Castelain	philippe.castelain@health.fgov.be philippe.castelain@sciensano.be	+32 2 524 72 64 +32 2 642 50 98

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Federal Public Service Health, Food Chain Safety and Environment (**FPS HFCSE**) DG Animals, Plants and Foodstuffs Department Plant Protection and Fertilising Products Avenue Galilée 5/2 1210 Brussels Belgium	FOD Volksgezondheid, Veiligheid van de Voedselketen en Leefmilieu (**FOD VVVL**) Directoraat Generaal Dier, Plant en Voeding Dienst Gewasbeschermingsmiddelen en Bemestingsproducten Galileelaan 5/2 1210 Brussel België	Service Public Fédéral Santé publique, Sécurité de la Chaîne alimentaire et Environnement (**SPF SPSCE**) Direction générale Animaux, Végétaux et Alimentation Service Produits Phytopharmaceutiques et Fertilisants Avenue Galilée 5/2 1210 Bruxelles Belgique
Sciensano Unit Risk & Health Impact Assessment Juliette Wytsmanstraat 14 B-1050 Brussels Belgium	**Sciensano** Risico- en gezondheidsimpactevaluatie Juliette Wytsmanstraat, 14 B-1050 Brussel België	**Sciensano** Evaluation des risques et de l'impact sur la santé Rue Juliette Wytsman 14 B-1050 Bruxelles, Belgique